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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,778	09/21/2005	Oliver German Perez Martin	LEXSA.P32	2870
28752 7590 08/17/2009 LACKENBACH SIEGEL, LLP LACKENBACH SIEGEL BUILDING 1 CHASE ROAD SCARSDALE, NY 10583				
EXAMINER				
SWARTZ, RODNEY P				
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1645				
MAIL DATE		DELIVERY MODE		
08/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,778

Applicant(s)

PEREZ MARTIN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-19, 21-29, 31-39, 41-55, 57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-19, 21-29, 31-39, 41-55, 57 and 58 is/are rejected.
- 7) ☒ Claim(s) 1, 35 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Office Action, received 14 October 2008, is acknowledged. Claim 9 has been amended. Claims 5, 20, 30, 40 and 56 have been cancelled. New claims 57 and 58 have been added.
2. Claims 1-4, 6-19, 21-29, 31-39, 41-55 and 57-58 are pending and under consideration.

Rejections/Objections Withdrawn or Moot

3. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.
4. The rejection of claims 5, 20, 30 and 40 under 35 U.S.C. 112, first paragraph, scope of enablement for a vaccine composition containing proteolipidic cochlear structures obtained from vesicles found in the outer membranes of any/all live microorganisms, is moot in light of the cancellation of the claims.
5. The objection to replacement Figure 7 is withdrawn in light of the new replacement figure.
6. The objection to claim 1 is withdrawn in light of the amendment of the claim.
7. The objection to claims 2-4 and 27-29 is withdrawn in light of the amendment of the claims.
8. The objection to claim 7 is withdrawn in light of the amendment of the claim.
9. The objection to claim 8 is withdrawn in light of the amendment of the claim.
10. The objection to claim 9 is withdrawn in light of the amendment of the claim.
11. The objection to claim 12 is withdrawn in light of the amendment of the claim.
12. The objection to claim 14 is withdrawn in light of the amendment of the claim.
13. The objection to claim 30 is moot in light of the cancellation of the claim.

14. The objection to claim 56 is moot in light of the cancellation of the claim.
15. The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite for "obtained from in the outer membranes", is withdrawn in light of the amendment of the claim.
16. The rejection of claims 25, 35 and 45 under 35 U.S.C. 112, second paragraph, as being indefinite for "derived from", is withdrawn in light of the amendment of the claims.
17. The rejection of claim 56 under 35 U.S.C. 112, second paragraph, as being indefinite for "derived from", is moot in light of the cancellation of the claim.
18. The rejection of claims 2-4, 17-19, 27-29 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for "pathogens associated molecular pattern", is withdrawn in light of the amendment of the claims.

Drawings

19. Figures 11-29 are objected to because the originally filed drawings contained 29 figures. The replacement drawings received 4 April 2007, containing 29 figures, changed the figures numbered 11-29 (deleting originally filed figure 11). The replacement drawings, received 14 July 2008, contain only 28 figures.

The examiner requires clarification concerning the disparity of figures originally submitted on 26 May 2005 and those submitted on 4 April 2007 and 14 July 2008.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining

figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

20. The objection to replacement Figure 19 is maintained until disparity of figures is clarified.

21. The objection to replacement Figure 24 is maintained until disparity of figures is clarified.

22. The objection to replacement Figure 25 is maintained until disparity of figures is clarified.

23. The objection to replacement Figure 28 is maintained until disparity of figures is clarified.

24. The objection to replacement Figure 29 is maintained until disparity of figures is clarified.

Rejections Maintained

25. The rejection of claims 37, 38, and 53 under 35 U.S.C. 112, second paragraph, as being indefinite for "associated to", is maintained for reasons of record.

Applicants argue that the claim amendments obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive because the claims have not been amended and the phrase remains.

26. The rejection of claims 1-4, 6-19, 21-29, 31-39 and 41-55 under 35 U.S.C. 112, first paragraph, scope of enablement for a vaccine composition containing proteolipidic cochlear structures obtained from vesicles found in the outer membranes of any/all live microorganisms, is maintained for reasons of record.

Applicants argue that the amendment of the claims to recite "selected from the group consisting of bacterial, protozoan or animal cell organism and additionally contain one or more antigens" obviates the rejection.

The examiner has considered applicants' argument in light of the amendments, but does not find it persuasive. The claims remain drawn to a vaccine composition containing proteolipidic cochlear structures obtained from the outer membrane vesicles of any/all bacterial, protozoan or animal cell organism. The specification does not provide sufficient examples for this extremely broad scope, i.e., that any bacterial, protozoan or animal cell organism can be utilized as a source for cochlear structures as vaccines. The limited number of examples does not provide enough support for the proposition that the vaccine qualities are universal.

27. The objection to the specification for new matter is maintained until such time as the disparity of the number of figures is clarified, see *supra*.

28. The rejection of claims 18, 19 and 28 under 35 U.S.C. 112, second paragraph, as being indefinite for "molecular pattern are", is maintained for reasons of record.

Applicants' argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive because the phrase remains.

29. The rejection of claims 19, 29 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for "peptyglycane", is maintained for reasons of record.

Applicants' argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive because the wording remains in claim 19 and it was replaced in claims 29 and 39 with "peptidoglycon" which is unclear.

30. The rejection of claims 4, 19, 29 and 39 under 35 U.S.C. 112, second paragraph, as being indefinite for "lipophosphoglycane", is maintained for reasons of record.

Applicants' argue that the amendment of the claims obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive because the wording remains, and applicants' reply presented no explanation.

31. The rejection of claim 46 under 35 U.S.C. 112, second paragraph, as being indefinite for "and adding a non-ionic detergent is added", is maintained.

Applicants argue that the amendment of the claim obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. As newly amended, the recitation remains indefinite as "adding a non-ionic detergent is in a concentration". It appears that the word "is" should also have been deleted.

Claim Objections

32. Claim 1 is objected to because of the following informalities: line 4, "additionally contain" should be "additionally containing". Appropriate correction is required.

33. Claim 35 is objected to because of the following informalities: line 2, "a tumor cell vesicles" should be either "a tumor cell vesicle" or "tumor cell vesicles". Appropriate correction is required.

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34. Claim 45 is objected to because of the following informalities: line 2, "a tumor cell vesicles" should be either "a tumor cell vesicle" or "tumor cell vesicles". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35. Newly added claims 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising cochlear structures for production of antibodies or for treating leishmaniasis, does not reasonably provide enablement for the extremely broad scope of the instant claims, i.e., a vaccine composition containing proteolipidic cochlear structures obtained from vesicles found in the outer membranes of any/all live microorganisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of

experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is a vaccine composition comprising proteolipidic cochlear structures obtained from vesicles found in the outer membranes of live microorganisms.

The state of the prior art for vaccine compositions varies, depending on the type of microorganism involved. Thus, there is a lack of predictability in the art that *a priori* any composition comprising proteolipidic cochlear structures as claimed would result in preventing disease due to the microorganism, because there is a lack of predictability that a composition of outer membranes is sufficient for a vaccine. For example, see Wang et al, concerning tuberculosis vaccines, and Gallo, concerning HIV vaccines.

The amount of direction or guidance present only shows that claimed structures from *L. major* reduce the number of indurations in mice, or that various *in vitro* tests are altered. The specification does not provide sufficient support for the extremely broad scope of the instant claims, i.e., a vaccine composition comprising proteolipidic cochlear structures obtained from vesicles found in any/all live microorganisms.

Thus, the scope of the instant claims constitutes merely an invitation to experiment without a reasonable expectation of success.

Conclusion

36. No claims are allowed.

37. Applicant's amendment necessitated the new ground(s) of rejection or objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 17, 2009